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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/663,777 | 09/17/2003 | Ricardo Gamboa | | 2957 |

7590 12/13/2005
RICARDO GAMBOA
Calle 8 No 823 Entre 523 Bis Y 524
TOLOSA, 1900
ARGENTINA

EXAMINER

CHATTOPADHYAY, URMI

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3738

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/663,777 | Applicant(s) GAMBOA, RICARDO | |
| | Examiner Urmi Chattopadhyay | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003 and 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “inferior end (2a)” mentioned on page 12, line 22, “MM axis” mentioned on page 15, line 18, and “distal end (API)” mentioned on page 16, line 16 are not shown in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: “b” in Figure 2 is not mentioned in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

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amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

On line 1 of the abstract, "Asymmetric", "Intracardiac" and "Device" should not be capitalized.

4. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are described below. The specification is generally indefinite because it appears to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic

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errors. The following are only a few examples of errors that need correction. It is applicant's responsibility to review the entire specification and make all other necessary corrections.

- a) Page 2, line 3 and page 9, line 19, "Fenestrated Asymmetric Intracardiac Device" should be changed to --fenestrated asymmetric intracardiac device--.
- b) Page 7, line 5, --a-- should be inserted before "hospital".
- c) Page 7, line 7, --to-- should be inserted before "today".
- d) Page 8, line 7, "cavopulmonar" should be changed to --cavopulmonary--.
- e) Page 10, lines 4-5, it is unclear what "selectively closure" means.
- f) Page 10, line 7, the comma after "conduit" must be changed to a period.
- g) Page 10, lines 9-10, it is unclear what "being more oval up to get a smaller diameter of the ellipse" means.
- h) Page 10, line 23, "venous" should be changed to --vein--.
- i) Page 10, the paragraph starting on line 11 includes run-on sentences and is wordy and confusing.
- j) Page 12, line 4, it appears from Figure 2 that "1SVC" should be changed to --SVC1--.
- k) Page 12, line 5, it appears from Figure 2 that "2SVC" should be changed to --SVC2--.
- l) Page 12, line 14, a period is missing after "(PTFE)".
- m) Page 12, line 16, it appears that "VSH" should be changed to --SVH--.
- n) Page 12, line 20 and page 15, lines 6-7, "Interventional Cardiologist" should be changed to --interventional cardiologist--.
- o) Page 13, line 1, the space between "view" and the comma should be deleted.
- p) Page 14, line 8, "an" must be changed to --and--.

q) Page 14, line 23, "another" should be changed to --other--.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 1 requires the first section to have a transverse section that is progressively "crushed". There is no support for this in the specification, which uses the term "flattened" instead of "crushed".

Claim Objections

6. Claims 4, 5 and 7 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits and are withdrawn from further consideration.

7. The claims do not conform to current U.S. practice. As set forth in M.P.E.P. § 608.01(m), "the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the Office of Patent Publication. Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i). There may be plural

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indentations to further segregate subcombinations or related steps.” Also, the claim should include a preamble, transitional phrase, and body, as set for in M.P.E.P. § 2111.02 and 2111.03.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The following are only a few examples of indefiniteness in the claims. It is applicant responsibility to review each claim and make any additional necessary corrections.

10. Claim 1, lines 4-5, it is unclear what “a same warped axial ace in the space form by a conduit section” means.

11. Claim 1 recites the limitation "the quoted axes" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 1, line 12, it is unclear what is meant by “fenestration selectively closure”.

13. Claim 1, lines 15-16, “along the warped axis, growing oval up to get a diameter smaller than the ellipse, between 10-13 mm” is confusing, and it is unclear if it is referring to the first

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inferior section or the second superior section. It appears from the specification that it should be referring to the first inferior section.

14. Claim 1, lines 20-22, "When this second section reaches the smallest area section (10-13mm), it bifurcates in two branches, being one of these branches longer and the transversal sections substantially circular" is very similar to and seems repetitive of the previous clause. It is unclear how it further limits the claimed invention.

15. Claim 6, line 6, it is unclear what is meant by "it forms a short permeable and when the blood flows".

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Zarins et al. (USPAP 2003/0204242).

Zarins et al. disclose an endoluminal prosthetic assembly with all the elements of claim 1. Because it meets all the claimed structural elements of the body, as best understood by the examiner, the endoluminal prosthetic assembly is structurally capable of providing as a fenestrated asymmetric intracardiac device for the completion of total cavopulmonary anastomosis through cardiac catheterization. Because the claims do not conform to current U.S.

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practice, it is unclear if what follows the first period in each claim is a claimed limitation of the invention or not. See Figures 3A, 3B and 5 for first inferior section including a substantially circular inferior end (61) and a fenestration (60), followed by a second superior section. Both sections share the same longitudinal axis, are flexible to achieve a curvature between 35 and 45 degrees, and include an impermeable polymeric covering (57). See paragraph [0025]. The second superior section bifurcates into a longer branch (51) and a short appendix (52), forming a distorted "Y". With respect to the device being used in the heart, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, which it is, then it meets the claim.

Claims 2, 3 and 6, see paragraph [0025] and Figure 5 for first and second sections forming a unique tubular body, and being made of a mesh of threads, the inferior first section including a mesh span (61), and the longer branch (51) including an impermeable polymeric material (57).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

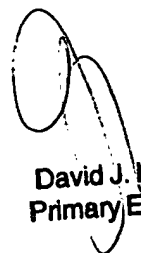
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner